Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of local induction of herbal formulation on muscle pain and muscle function after a single bout of soccer activity in male soccer players

Protocol summary

Study aim

To evaluate the effect of a topical herbal ointment on muscle performance, delayed onset muscle soreness, and mental well-being in professional football players after a single bout of football activity.

Design

Randomized, double blind, placebo controlled, parallel group clinical trial in professional male football players.

Settings and conduct

The study will be conducted in professional football players in the team training setting. After informed consent, participants will be screened and randomly assigned to intervention or control groups. Outcome assessors and participants will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Professional male football players in the predefined age range; regular football training experience; no injury or disease affecting test performance; no allergy to plants, essential oils, or ointment ingredients; no skin lesion at the application site; no use of anti inflammatory drugs, analgesics, or recovery methods outside the protocol; withdrawal in case of injury, skin reaction, protocol violation, absence, or personal request.

Intervention groups

The intervention group will receive a topical ointment containing mint, rosemary, thyme, and pennyroyal essential oils. The control group will receive a placebo ointment with similar appearance and application method. Both groups will be prohibited from using anti inflammatory drugs, analgesics, or recovery methods outside the protocol.

Main outcome variables

Countermovement jump performance; reactive strength index; delayed onset muscle soreness; mental well-being at 12, 36, and 60 hours after football activity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260908070975N1**
Registration date: **2026-09-12, 1405/06/21**
Registration timing: **prospective**

Last update: **2026-09-12, 1405/06/21**
Update count: **0**

Registration date

2026-09-12, 1405/06/21

Registrant information

Name

Erfan Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

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erfan.eslami@iau.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of local induction of herbal formulation on muscle pain and muscle function after a single bout of soccer activity in male soccer players

Public title
The effect of herbal ointment on delayed onset pain in athletes

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being a boy and being within the specified age range of the study Being a footballer and having a minimum amount of regular football practice experience No acute or chronic injury to the lower extremities, back, or pelvis within the past three months Not having cardiovascular, neurological, musculoskeletal, or skin diseases that affect the performance of the tests. No history of known allergies to plants, essential oils, cosmetics, or ingredients in the ointment No wounds, scratches, inflammation, infection, eczema, or skin lesions at the site of ointment application. Refrain from taking anti-inflammatory drugs, painkillers, or other recovery methods not permitted according to the research plan.

Exclusion criteria:
The occurrence of any sports injury, illness, skin reaction, sensitivity, redness, itching, burning, swelling, or abnormal pain at the site of ointment application, failure to comply with research guidelines, absence from any of the assessment stages, use of medication or use of recovery methods outside the protocol, as well as the participant's personal request, will be among the exclusion criteria from the study. Despite the natural origin of the ingredients used, there is a possibility of local reactions such as redness, itching, burning, a feeling of warmth or coolness, dry skin, inflammation, swelling or allergic reactions. For this reason, an initial skin test will be performed to check the tolerance of the ointment before starting the main intervention.

Age
From **14 years** old to **16 years** old

Gender
Male

Phase
1

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be randomly allocated in a 1:1 ratio to the intervention group (herbal ointment) or the control group (placebo) after providing informed consent. The random allocation sequence will be generated using permuted random blocks with variable block sizes by a person independent of participant recruitment and outcome assessment, using random-number-generation software. The unit of randomization will be the individual participant. Allocation concealment will be ensured by using sequentially numbered, opaque, sealed envelopes containing the group codes, which will be opened only after a participant has been definitively enrolled. No stratification will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted as a double-blind, placebo-controlled trial. Participants will receive either the herbal ointment or a placebo ointment that is identical in appearance, color, odor, texture, packaging, and method of application. The intervention and placebo products will be labeled with anonymous codes by a person independent of participant recruitment, intervention delivery, outcome assessment, and data analysis. Participants and investigators will remain unaware of group allocation throughout the trial. Data will be analyzed using coded group labels, and the allocation code will be disclosed only after completion of the final data analysis. In the event of a serious adverse reaction requiring clinical management, the relevant allocation code may be unblinded when necessary.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University, Tehran Central Branch

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NO 45,Erfaghi, sotani, tehranpars

City
Tehran

Province
Tehran

Postal code
1656836781

Approval date
2026-09-07, 1405/06/16

Ethics committee reference number
IR.IAU.CTB.REC.1405.061

Health conditions studied

1

Description of health condition studied
DOMS

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Countermovement jump height in centimeters
Timepoint
Before intervention, and at 12, 36, and 60 hours after football activity
Method of measurement
Measured using the countermovement jump test and recorded as the highest jump height in centimeters

2

Description
Reactive strength index
Timepoint
Before intervention, and at 12, 36, and 60 hours after football activity
Method of measurement
Measured using a jump test and calculated from jump height and ground contact time

3

Description
Delayed onset muscle soreness intensity measured by visual analog scale score
Timepoint
Before intervention, and at 12, 36, and 60 hours after football activity
Method of measurement
Assessed using a visual analog scale

4

Description
Mental well-being including pain, fatigue, sleep, mood, and stress
Timepoint
Before intervention, and at 12, 36, and 60 hours after football activity
Method of measurement
Assessed using a player well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will receive a topical ointment containing mint, rosemary, thyme, and pennyroyal essential oils. The ointment will be applied topically to the target area in a standard dose and manner.
Category
Rehabilitation

2

Description
Control group: The control group will receive a placebo ointment with the same appearance, color, odor, texture, and packaging. The placebo will be applied in the same manner and amount as the intervention ointment.irct
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
PAYAME MOKHABERAT
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Islamic Azad University

Proportion provided by this source

10

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

MOHAMAD ALI AZARBAYJANI

Position

Professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data, along with the study protocol, statistical analysis plan, informed consent form, final clinical study report, analysis code, and data dictionary, will be shared.

When the data will become available and for how long

Access will begin 6 months after publication of the final study results and will remain available for 5 years thereafter.

To whom data/document is available

Qualified academic researchers, faculty members, and other eligible investigators who submit a formal request.

Under which criteria data/document could be used

Data may be used only for scientific analysis, reanalysis, and non-commercial research. Access is subject to

confidentiality, no attempt to re-identify participants, and approval by the principal investigator.

From where data/document is obtainable

Requests should be submitted to the principal investigator via email or formal correspondence.

What processes are involved for a request to access data/document

Requests will be reviewed, and after scientific evaluation and approval, de-identified data or documents will be provided. The usual response time is 2 to 4 weeks.

Comments

Data will be provided only for scientific purposes and in accordance with research ethics principles. 12